

Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER; the Director and Deputy Director, Office of Generic Drugs, Office of Pharmaceutical Science, CDER; and the Director and Deputy Director, Office of Compliance, CDER.

(e) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Compliance, CBER.

[56 FR 51170, Oct. 10, 1991, as amended at 57 FR 40317, Sept. 3, 1992; 62 FR 2556, Jan. 17, 1997; 62 FR 67272, Dec. 24, 1997]

#### **§ 5.58 Orphan products.**

(a) The Director, Office of Orphan Products Development, Office of the Commissioner, is authorized to issue notices, and amendments thereto, inviting sponsorship for orphan products (human and animal drugs, biological products, and medical devices) and submission of:

(1) Notices of claimed investigational exemption for a new drug or new drug applications;

(2) Notices of claimed investigational exemption for a new animal drug or new animal drug applications;

(3) Applications for establishment and product licenses for biological products; or

(4) Applications for an investigational device exemption or premarket approval applications for medical devices, as appropriate.

(b) The Director, Office of Orphan Products Development, Office of the Commissioner, is authorized:

(1) To determine whether there is reason to believe that a drug is a drug for a disease or condition that is rare in the United States under section 525(a) of the Federal Food, Drug, and Cosmetic Act (the act) and to designate such drug as a drug for a rare disease or condition under section 526(a) of the act.

(2) To issue holders of approved applications or licenses notice and opportunity for the submission of views under section 527(b)(1) of the act.

(3) To encourage sponsors of an investigational new drug for a rare disease or condition to design protocols for clinical investigations to permit the addition to the investigation of persons with the disease or condition under section 528 of the act.

(c) The following officials are authorized to provide sponsors, under section 525(a) of the act, with recommendations for nonclinical or clinical investigations believed to be necessary for a drug for a rare disease or condition to be approved or licensed:

(1) For drugs under their jurisdiction:

(i) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(ii) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(iii) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(2) For biological products under their jurisdiction:

(i) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(ii) The Director and Deputy Director, Office of Biological Product Review, CBER.

(iii) The Directors and Deputy Directors of the divisions in the Office of Biological Product Review, CBER.

[48 FR 40703, Sept. 9, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 49 FR 27489, July 5, 1984; 50 FR 19341, May 8, 1985; 54 FR 8318, Feb. 28, 1989; 55 FR 51688, Dec. 17, 1990; 62 FR 2556, Jan. 17, 1997]

#### **§ 5.59 Approval, disapproval, or withdrawal of approval of applications for investigational device exemptions.**

(a) For medical devices assigned to their respective organizations, the following officials are authorized to approve, disapprove, or withdraw approval of applications for investigational device exemptions submitted under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act):

(1) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), the Director